NOV 2 2 2000

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) **Submitter's name, address, telephone number, contact person:**

Regulatory Management Services
16303 Panoramic Way
San Leandro CA 94578-1116
Gary J. Allsebrook
Regulatory Affairs Consultant
Telephone: (510) 276-2648
Fax: (510) 276-3559
Email: regman1@home.com
Prepared: October 11, 2000

2) **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/Usual Name:
Diagnostic Ultrasound System and Accessories

Proprietary Name:
Voluson 730 Diagnostic Ultrasound System and Transducers.

Classification Names:	FR Number	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) **Identification of the predicate or legally marketed device:**
Medison America, Inc believes that Voluson 730 Ultrasound System is substantially equivalent to the currently marketed Voluson 530 System,K940942 and ATL HDI 5000 System (Level 10HDI), K961459.

4) **Device Description:**
The Voluson 730 Ultrasound System is a general purpose, mobile, software controlled diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B-mode, M-mode, Color Flow Doppler (CFM), Continuous Wave (CW) Doppler, Pulsed Wave (PW) Doppler , Power (Amplitude) Doppler (PD) and 3D Volume imaging mode , or as a combination of these modes. The Voluson 730 also gives the operator the ability to measure anatomical structures and

offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The Voluson 730 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

23 different models of transducers are available and any three may be connected at the same time (plus one pencil probe). In addition to the initial operational settings for each transducer preprogrammed in the system, user-customized parameter settings for each transducer may be inserted by the operator and stored for recall as needed via the system control panel. Customization includes transmit focusing, filtering, image enhancement processing, dynamic window curve selection. Controls are also provided to select display format (single and various combinations), to activate zoom features, and to utilize the cine loop function. Patient contact materials have been used in FDA cleared probes or have passed biocompatibility tests (NamSA).

The Voluson 730 uses digital beamforming technology and supports a variety of Linear, Curved and Phased Array probes (plus pencil probe) for wide variety of applications. It is an ultrasound scanner, which provides high resolution, high penetration performance, and various measurement functions. Probes are supported in frequencies from 2.0 MHz to 16.0 MHz. These probes can be applied to a variety of clinical applications such as abdominal, obstetrical, cerebrovascular, peripheral vascular, gynecological and fertility, small parts, neonatal, intraoperative, vascular, abdominal surgery, laparoscopic, muskoloskeletal, transcranial Doppler, pediatric general imaging, prostate, adult cardiology and pediatric cardiology and transesophagael use. The Voluson 730 provides high quality images and various measuring functions. The same clinical uses were cleared for the predicate devices: Kretztechnik Combison/Voluson 530D Ultrasound System K940942 and ATL HDI 5000 Ultrasound System (Level 10 HDI) K961459.

The system can be used to measure distances and calculate areas, circumferences and volumes, as well as calculate the date of delivery by using BPD (biparietal diameter), OFD (occipito-frontal diameter), HC (head circumference), AC (abdominal circumference), AD (abdominal diameter), FL (femur length), CRL (crown rump length), APTD (anteroposterior trunk diameter), TTD (transverse trunk diameter), GS (gestational sac), and LMP (last menstural period.) etc., Cardiac Analysis (volume by area/length, Simpson biplane and singleplane, M-mode analysis, Doppler peak and mean gradients, pressure half time , E/A ratio and continuity equation) and vascular Analysis (resistance index,pulsitility index, % stenosis, ICA/CCA ratio, VF). Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. Operating Modes of Voluson 730 are B, B/B, B/Quad, M, B/M , PW,B/PW,CW,B/CW, CFM, PD, B/PW/CFM, B/PW/PD, B/CW/CFM,B/CW/PD and 3D Imaging mode. The modes of M use the Sweep method which has its images flow from the left to the right. Voluson 730 supports the Cine function (capable of

storing up to 256 sequential images) and real-time zoom function to the region-of-interest. The system provides the ability to perform remote viewing of images without compression, via Dicom 3.0A compatible output. Management of patient history is possible by image-filing function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing.

The Voluson 730 Ultrasound System meets the following electromechanical safety standards:

- EN 60601-1 (IEC 601-1,) European Norm, Medical Electrical Equipment
- UL 2601-1, Underwriters Laboratories Standards, Medical Electrical Equipment
- C22.2 No. 601.1, Canadian Standards Association, Medical Electrical Equipment
- CEI/IEC 1157:1992, International Electrotechnical Commission, Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment
- EN 60601-1-2 (IEC 601-1-2,) European Norm, Collateral Standard: Electromagnetic compatibility
- Compliant with the European Medical Device Directive Certificate issued by TUV.

5) Intended Use:

The Voluson 730 System intended uses as defined FDA guidance documents are:

- Abdominal
- Obstetrical
- Neonatal cephalic
- Adult cephalic
- Peripheral vascular
- Gynecological and fertility
- Small parts (breast, thyroid, parathyroid, penis, testes etc)
- Intraoperative vascular
- Intraoperative neurological
- Abdominal surgery
- Muscular skeletal conventional
- Muscular skeletal superficial (skin)
- Transcranial doppler
- Pediatric general imaging
- Laparoscopic
- Prostate
- Trans-Rectal
- Trans-Vaginal
- Adult cardiology
- Pediatric cardiology

- Transesophagael
- Neonatal

Typical examinations performed using the system are:

- General abdominal and pelvic studies including organ surveys, assessment, and retro-peritoneal cavity studies.
- Study of small parts including breasts, shoulders, thyroid, and the abdominal wall.
- Pediatric scans of organs and bony structures.
- Peripheral vascular applications including carotid arteries, legs, arms, feet, and penile artery.
- Monitoring procedures for infertility studies (other than in vitro fertilization).
- First, second and third trimester pregnancy studies.
- Prostate, prostate biopsy guidance, and rectal wall studies.
- Neonatal head studies.
- Transcranial studies of middle cerebral arteries, internal carotid artery, and vertebral arteries.
- Cardiac studies in adults and children.
- Biopsy guidance for tissue or fluid sampling.
- Conventional podiatry scans.
- Intraoperative application including soft tissue structures.

6) Technological Characteristics:

This device operates identical to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D and M-mode, Continuous wave Doppler, Spectral Doppler, Color Doppler, Power Doppler, 3D images. Scanhead patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:	(Maximum Range)
I_{SPTA}	720 mW/cm2
MI	1.9

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2000

Medison America, Inc.
c/o Mr. Mark Job
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, Minnesota 55112-1891

Re: K003525
Voluson 730 Diagnostic Ultrasound System
Regulatory Class: II
21 CFR §892.1550/Procode: 90 IYN
21 CFR §892.1560/Procode: 90 IYO
21 CFR §892.1570/Procode: 90 ITX
Dated: November 13, 2000
Received: November 15, 2000

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Voluson 730 Ultrasound System, as described in your premarket notification:

Transducer Model Number

SP 4-10 4-10 MHz / 50mm / Linear Array
SP 6-12 6.0-12.0 MHz / 40mm / Linear Array
SP 10-16 10-16 MHz / 30mm / Linear Array
IOL 5-9 5.0-9.0 MHz / 38mm / Linear Array
AB 2-5 2.0-5.0 MHz / 40R / 85D / Curved Array

AB 4-8 4.0-8.0 MHz / 40R / 70D / Curved Array
IOC 4-8 4.0-8.0 MHz / 40R / 60D / Curved Array
LAP 5-8 5.0-8.0 MHz / 40R / 40D / Curved Array
IC 5-9 5.0-9.0 MHz / 10R / 150D / Curved Array
PA 2-5 2.0-5.0 MHz / 90D / Phased Array
PA 4-7 4.0-7.0 MHz / 90D / Phased Array
PA 6-8 6.0-8.0 MHz / 90D / Phased Array
VSP 6-12 6.0-12 MHz / 40mm / 3D Linear Array
RSP 6-12 6.0-12 MHz / 40mm / 3D Linear Array
RAB 2-5 2.0-5.0 MHz / 40R / 85D / 3D Curved Array
RAB 4-8 4.0-8.0 MHz / 40R / 70D / 3D Curved Array
RIC 5-9 5.0-9.0 MHz / 10R / 150D / 3D Curved Array
RRE 6-10 6.0-10.0 MHz / 10R / 180D / 3D Curved Array
VPA 2-5 2.0-5.0 MHz / 90D / 3D Phased Array
VPA 4-7 4.0-7.0 MHz / 90D / 3D Phased Array
VTE 4-7 4.0-7.0 MHz / 90D / 3D Phased Array
SCW 2.0 2.0 MHz / Pencil Probe
PCW 4.0 4.0 MHz / Pencil Probe

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

4.3 Indications for Use

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: **Voluson 730 Ultrasound System**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal *(See Note 7)*		N	N	N		N	N		Note 1	Notes 2,3,5
Abdominal		N	N	N		N	N		Note 1	Notes 2,3,5
Intra-Operative *(See Note 6)*		N	N	N		N	N		Note 1	Notes 2,3,5
Intraoperative Neurological		N	N	N		N	N		Note 1	Notes 2,3,5
Pediatric		N	N	N		N	N		Note 1	Notes 2,3,5
Small Organ *(See Note 4)*		N	N	N		N	N		Note 1	Notes 2,3,5
Neonatal Cephalic		N	N	N		N	N		Note 1	Notes 2,3,5
Adult Cephalic		N	N	N		N	N		Note 1	
Cardiac		N	N	N	N	N	N		Note 1	Notes 2,5,8
Transesophageal		N	N	N	N	N	N		Note 1	Notes 2,5,8
Transrectal		N	N	N		N	N		Note 1	Notes 2,3,5
Transvaginal		N	N	N		N	N		Note 1	Notes 2,3,5
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		Note 1	Notes 2,3,5
Laparascopic		N	N	N		N	N		Note 1	Note 3,5
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	Notes 2,3,5
Muscular-Skeletal Superficial		N	N	N		N	N		Note 1	Notes 2,3,5
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 2: 3D Imaging Mode
Note 3: Includes imaging for guidance of biopsy
Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.
Note 5: Harmonic Imaging
Note 6: Abdominal organs and peripheral vessel
Note 7: Includes infertility monitoring of follicle development
Note 8: Color M-mode

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

Indications For Use
510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **SP 4-10 4.0-10 MHz/50mm/Linear Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		Note 1	Note 5
Small Organ *(See Note 4)*		N	N	N		N	N		Note 1	Note 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		Note 1	Note 5
Laparascopic										
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	Note 5
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.
Note 5: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

Indications For Use 510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **SP 6-12 6.0-12 MHz/40mm/Linear Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		Note 1	Notes 3,5
Small Organ *(See Note 4)*		N	N	N		N	N		Note 1	Notes 3,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		Note 1	Notes 3,5
Laparascopic										
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	Notes 3,5
Muscular-Skeletal Superficial		N	N	N		N	N		Note 1	Notes 3,5
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 3: Includes imaging for guidance of biopsy
Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.
Note 5: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **SP 10-16 10-16 MHz/30mm/Linear Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ *(See Note 4)*		N	N	N		N	N		Note 1	Note 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial		N	N	N		N	N		Note 1	Note 5
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.
Note 5: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003525

Prescription Use ✓
(Per 21 CFR 801.109)

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **IOL 5 -9 5.0-9.0 MHz/38mm/Linear Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative *(See Note 6)*		N	N	N		N	N		Note 1	Note 5
Intraoperative Neurological		N	N	N		N	N		Note 1	Note 5
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 5: Harmonic Imaging
Note 6: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **AB 2-5 2.0-5.0 MHz/ 40R/85D/Curved Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal *(See Note 7)*		N	N	N		N	N		Note 1	Notes 3,5
Abdominal		N	N	N		N	N		Note 1	Notes 3,5
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 3: Includes imaging for guidance of biopsy
Note 5: Harmonic Imaging
Note 7: Includes infertility monitoring of follicle developement

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003525

Prescription Use ✓
(Per 21 CFR 801.109)

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **AB 4-8 4.0-8.0 MHz/40R/70D/Curved Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal *(See Note 7)*		N	N	N		N	N		Note 1	Notes 3,5
Abdominal		N	N	N		N	N		Note 1	Notes 3,5
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		Note 1	Notes 3,5
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	Notes 3,5
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 3: Includes imaging for guidance of biopsy
Note 5: Harmonic Imaging
Note 7: Includes infertility monitoring of follicle developement

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

Indications For Use

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **IOC 4 -8 4.0-8.0 MHz/40R/60D/Curved Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative *(See Note 6)*		N	N	N		N	N		Note 1	Note 5
Intraoperative Neurological		N	N	N		N	N		Note 1	Note 5
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 5: Harmonic Imaging
Note 6: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003525

Indications For Use

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **LAP 5 -8 5.0-8.0 MHz/40R/40D/Curved Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic		N	N	N		N	N		Note 1	Notes 5
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 5: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **IC 5-9 5.0-9.0 MHz/10R/150D/Curved Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal *(See Note 7)*		N	N	N		N	N		Note 1	Notes 3,5
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		Note 1	Notes 2,3
Transvaginal		N	N	N		N	N		Note 1	Notes 2,3
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 3: Includes imaging for guidance of biopsy
Note 5: Harmonic Imaging
Note 7: Includes infertility monitoring of follicle developement

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003525

Prescription Use ✓
(Per 21 CFR 801.109)

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **PA 2-5 2.0-5.0 MHz/ 90D/Phased Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N		Note 1	Notes 5,8
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		Note 1	Notes 5,8
Cardiac		N	N	N	N	N	N		Note 1	Notes 5,8
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 5: Harmonic Imaging
Note 8: Color M-Mode

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **PA 4-7 4.0-7.0 MHz/ 90D/Phased Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		Note 1	Notes 5,8
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		Note 1	Notes 5,8
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 5: Harmonic Imaging
Note 8: Color M-Mode

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003525

Prescription Use ✓
(Per 21 CFR 801.109)

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **PA 6-8 6.0-8.0 MHz/ 90D/Phased Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic		N	N	N	N	N	N		Note 1	Notes 5,8
Adult Cephalic										
Cardiac		N	N	N	N	N	N		Note 1	Notes 5,8
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 5: Harmonic Imaging
Note 8: Color M-Mode

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **VSP 6-12 6.0-12 MHz/40mm/3D Linear Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative *(See Note 6)*		N	N	N		N	N		Note 1	Notes 2,3,5
Intraoperative Neurological										
Pediatric		N	N	N		N	N		Note 1	Notes 2,3,5
Small Organ *(See Note 4)*		N	N	N		N	N		Note 1	Notes 2,3,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		Note 1	Notes 2,3,5
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial		N	N	N		N	N		Note 1	Notes 2,3,5
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 2: 3D Imaging Mode
Note 3: Includes imaging for guidance of biopsy
Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.
Note 5: Harmonic Imaging
Note 6: Abdominal organs

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

Indications For Use
510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **RSP 6-12 6.0-12 MHz/40mm/3D Linear Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative *(See Note 6)*		N	N	N		N	N		Note 1	Notes 2,3,5
Intraoperative Neurological										
Pediatric		N	N	N		N	N		Note 1	Notes 2,3,5
Small Organ *(See Note 4)*		N	N	N		N	N		Note 1	Notes 2,3,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		Note 1	Notes 2,3,5
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial		N	N	N		N	N		Note 1	Notes 2,3,5
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 2: 3D Imaging Mode
Note 3: Includes imaging for guidance of biopsy
Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes, pediatric and neonatal patients etc.
Note 5: Harmonic Imaging
Note 6: Abdominal organs

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,

Prescription Use _____
(Per 21 CFR 801.109)

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **RAB 2-5 2.0-5.0 MHz/40R/85D/3D Curved Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal *(See Note 7)*		N	N	N		N	N		Note 1	Notes 2,3,5
Abdominal		N	N	N		N	N		Note 1	Notes 2,3,5
Intra-Operative *(See Note 6)*										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	Notes 2,3,5
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 2: 3D Imaging Mode
Note 3: Includes imaging for guidance of biopsy
Note 5: Harmonic Imaging
Note 7: Includes infertility monitoring of follicle developement

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **RAB 4-8 4.0-8.0 MHz/40R/70D/3D Curved Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal (*See Note 7)*		N	N	N		N	N		Note 1	Notes 2,3,5
Abdominal		N	N	N		N	N		Note 1	Notes 2,3,5
Intra-Operative *(See Note 6)*		N	N	N		N	N		Note 1	Notes 2,3,5
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional		N	N	N		N	N		Note 1	Notes 2,3,5
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 2: 3D Imaging Mode
Note 3: Includes imaging for guidance of biopsy
Note 5: Harmonic Imaging
Note 6: Abdominal organs
Note 7: Includes infertility monitoring of follicledevelopement

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **RIC 5-9 5.0-9.0 MHz/10R/150D/3D Curved Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal *(See Note 7)*		N	N	N		N	N		Note 1	Notes 2,3,5
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic		N	N	N		N	N		Note 1	Notes 2,3,5
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		Note 1	Notes 2,3,5
Transvaginal		N	N	N		N	N		Note 1	Notes 2,3,5
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 2: 3D Imaging Mode
Note 3: Includes imaging for guidance of biopsy
Note 5: Harmonic Imaging
Note 7: Includes infertility monitoring of follicledevelopement

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **RRE 6-10 6.0-10.0 MHz/10R/180D/3D Curved Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal (Specify)										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		Note 1	Notes 2,3,5
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 2: 3D Imaging Mode
Note 3: Includes imaging for guidance of biopsy
Note 5: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **VPA 2-5 2.0-5.0 MHz/ 90D/3D Phased Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N		Note 1	Notes 2,5,8,
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		Note 1	Notes 2,5,8
Cardiac		N	N	N	N	N	N		Note 1	Notes 2,5,8
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 2: 3D Imaging Mode
Note 5: Harmonic Imaging
Note 8: Color M-Mode

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

Indications For Use

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **VPA 4-7 4.0-7.0 MHz/ 90D/3D Phased Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		Note 1	Notes 2,5,8
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		Note 1	Notes 2,5,8
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 2: 3D Imaging Mode
Note 5: Harmonic Imaging
Note 8: Color M-Mode

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **VTE 4-7 4.0-7.0 MHz/ 90D/ 3D Phased Array**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		Note 1	Notes 2,5,8
Transesophageal		N	N	N	N	N	N		Note 1	Notes 2,5,8
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/ Power Doppler
Note 2: 3D Imaging Mode
Note 5: Harmonic Imaging
Note 8: Color M-Mode

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003525

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **SCW 2.0 2.0 MHz / Pencil Probe**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003525

Prescription Use ✓
(Per 21 CFR 801.109)

Ultrasound Device Indications For Use Statement

510(k) Number:
Device Name: Voluson 730 Ultrasound System
Transducer: **PCW 4.0 4.0 MHz / Pencil Probe**

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric					N					
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E= added under Appendix E

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Prescription Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003525